United States Patent [19]

Binard et al.

[11] **3,860,007**

[45] ***Jan. 14, 1975**

[54] **CATHETER WITH SAFETY DEFLATION MEANS**

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[73] Assignee: **The Kendall Co.,** Walpole, Mass.

[*] Notice: The portion of the term of this patent subsequent to Apr. 10, 1990, has been disclaimed.

[22] Filed: **Feb. 20, 1973**

[21] Appl. No.: **333,926**

[52] **U.S. Cl.** ..... **128/349 B,** 128/246

[51] **Int. Cl.** **A61m 25/00**

[58] **Field of Search** ..... 128/348, 349 B, 349 BV, 128/350 R, 351, 344, 246, 325

[56] **References Cited**

UNITED STATES PATENTS

2,330,399	9/1943	Winder	128/349 B
2,912,981	11/1959	Keough	128/349 B
2,936,761	5/1960	Snyder	128/349 B
3,385,301	5/1968	Harautuneian	128/349 BV
3,495,594	2/1970	Swanson	128/349 BV

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Attorney, Agent, or Firm—Powell L. Sprunger

[57] **ABSTRACT**

A catheter including, a shaft having a proximal end, a distal end for insertion into a body cavity, a drainage eye adjacent the distal end of the shaft, and a main lumen extending from the drainage eye to the proximal end of the shaft for draining the cavity. The catheter has an inflatable retention balloon adjacent the distal end of the shaft for retaining the shaft in the cavity, an inflation lumen extending between the inside of the balloon and adjacent the proximal end of the shaft, and valve means for controlling inflation and deflation of the balloon. The catheter also has at least one separate deflation lumen communicating between the balloon and adjacent the proximal end of the shaft, in order that the balloon may be deflated through the deflation lumen by severing the catheter shaft adjacent its proximal end when the inflation lumen is obstructed.

5 Claims, 7 Drawing Figures

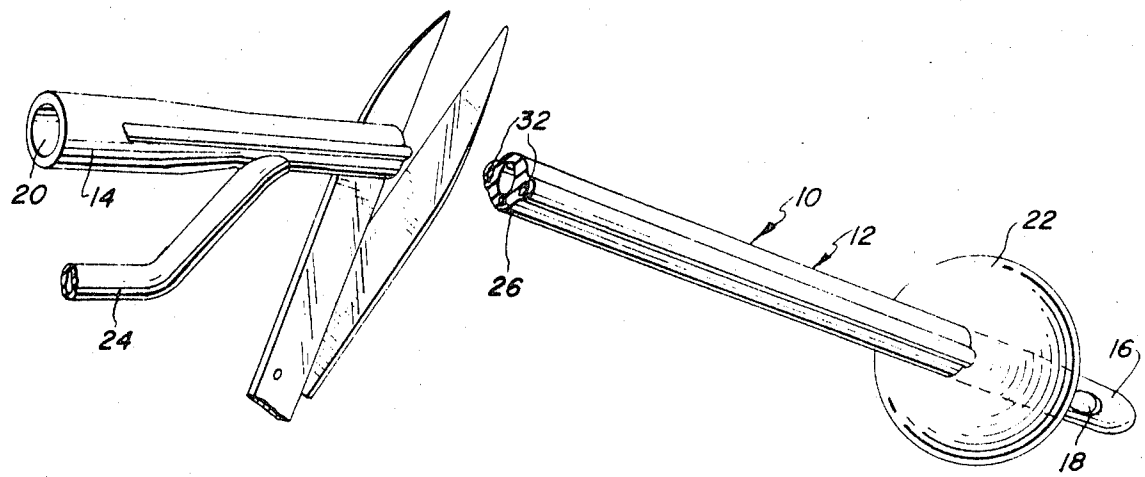


FIG. 1

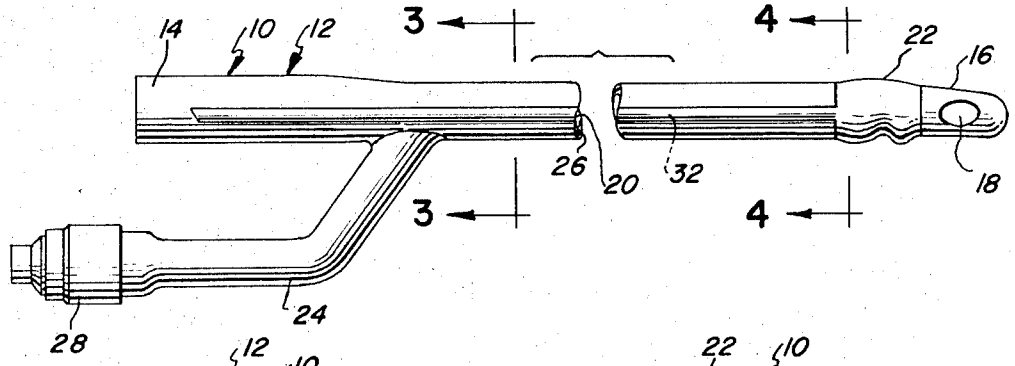


FIG. 3

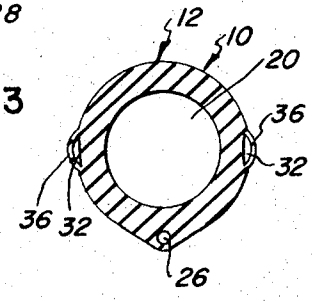


FIG. 4

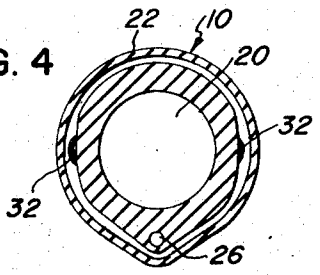


FIG. 2

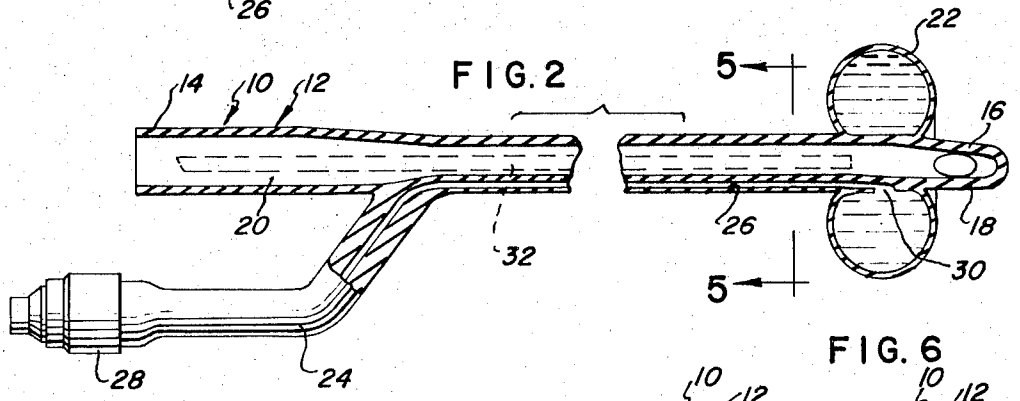


FIG. 6

FIG. 5

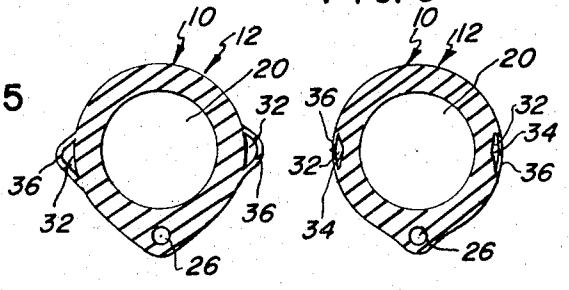
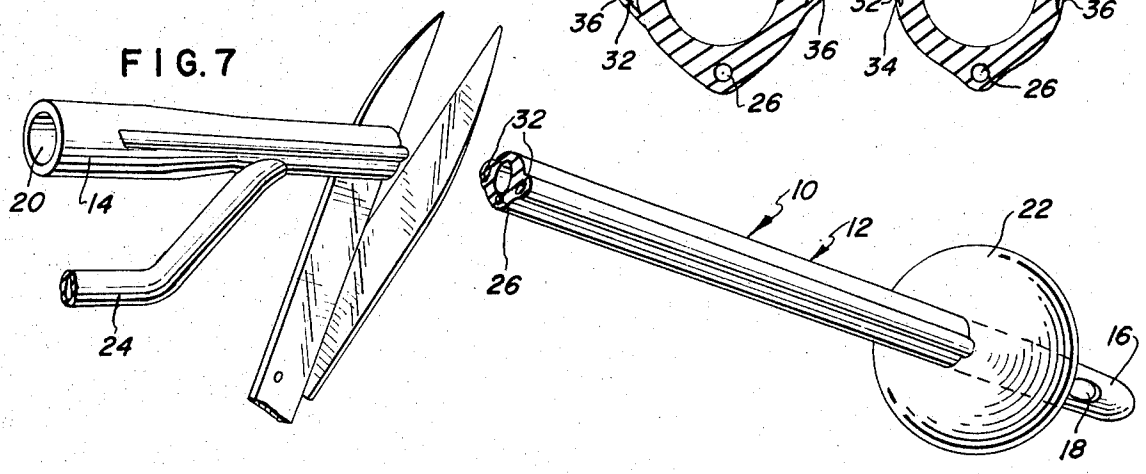


FIG. 7



CATHETER WITH SAFETY DEFLATION MEANS

CROSS-REFERENCE TO RELATED APPLICATION

"Body-Retained Catheter," Ser. No. 187,370, filed Oct. 7, 1971, issued as U.S. Pat. No. 3,726,283 invented by the applicants of the present application, and assigned to the assignee of the present application.

BACKGROUND OF THE INVENTION

The present invention relates to catheters.

Catheters, such as urinary drainage catheters, have long been used to drain a body cavity of a patient. As an example of a catheterization procedure, the distal end of a urinary catheter is inserted through the urethra into the patient's bladder, such that the proximal end of the catheter extends outside of the patient's body. The catheter has a drainage eye adjacent its distal end and a main lumen extending from the drainage eye to the proximal end of the catheter, in order that liquid drains from the bladder through the eye and main lumen of the catheter. Such a catheter usually has an inflatable retention balloon adjacent its distal end, and an inflation lumen communicating between the balloon and valve means adjacent the proximal end of the catheter to control inflation and deflation of the balloon. The balloon is inflated in the bladder through the valve means and inflation lumen to prevent the inadvertent removal of the catheter from the bladder. When catheterization has been completed, the ballon is deflated through the inflation lumen and valve means to permit removal of the catheter from the patient.

Experience has shown that one of the most common problems associated with such retention catheters is that the balloon may fail to deflate after catheterization is complete. A number of different causes may result in this failure. First, the standard latex Foley catheter is made by a series of dipping procedures, and the inflation lumen is formed by a mandrel positioned in the wall of the catheter. The balloon is formed by making a final dip of the catheter over an area covered with bentonite, preventing adherence of the layer formed by the last dip and the underlying catheter shaft. After the dipping procedure has been completed, the mandrel is removed from the inflation lumen of the catheter.

A residual of bentonite remaining under the balloon may later clog the inflation lumen after inflation of the balloon, and thus prevent deflation of the balloon. Also, the series of laminations formed by the series of dips may sometimes delaminate in the region of the inflation lumen, and block the inflation lumen. Usually the balloon may readily be inflated by a syringe when such conditions exist, since substantial inflation pressures are created by a syringe. However, successful deflation of the balloon is primarily dependent upon the substantially less pressures generated by the expanded balloon, since suction created by the syringe during deflation frequently accentuates the problem leading to failure, such as delamination of the catheter. It is known that the retention balloons frequently inflate assymetrically, and one other possible cause of deflation failure is that a portion of the balloon may cover and close the end of the inflation lumen which terminates in an opening under the balloon. Also, the valve means has been known to malfunction during deflation of the balloon. Another possible cause for failure results from incomplete punching or cutting of the opening communicating between the inflation lumen and the balloon, which may form a flap like member in the opening acting as a one-way valve and preventing deflation.

Since the inflated balloon is too large to pull through the patient's urethra, when the balloon fails to deflate, the physician or other attendant often severs the catheter at a point near its entry into the urethra. If the obstruction is intermediate the point of severance of the proximal end of the catheter, the balloon will deflate through the severed inflation lumen. However, more frequently, the obstruction is intermediate the point of severance and the balloon. In such a case, the balloon will fail to deflate, and further procedures are necessary to deflate the balloon. For example, the physician may pass a wire having a sharp tip through the inflation lumen in an attempt to puncture the balloon, may introduce a chemical which is incompatible with the balloon, such as ether, through the inflation lumen into the balloon in order to cause bursting of the balloon, or may resort to a surgical procedure to obtain access to the balloon.

It is apparent that failures associated with balloon deflation failure are not only inconvenient, but are also traumatic to both the physician and the patient.

SUMMARY OF THE INVENTION

A principal feature of the present invention is the provision of a catheter of simplified construction having safety deflation means for a retention balloon on the catheter.

The catheter of the present invention includes a shaft having a proximal end, a distal end for insertion into a body cavity, a drainage eye adjacent the distal end of the shaft, and a main lumen extending from the drainage eye to the proximal end of the shaft for draining the cavity. The catheter has an inflatable retention balloon adjacent the distal end of the shaft for retaining the shaft in the cavity, an inflation lumen extending between the inside of the balloon and adjacent the proximal end of the shaft, and valve means for controlling inflation and deflation of the balloon. The catheter also has at least one separate deflation lumen communicating between the balloon and adjacent the proximal end of the shaft.

Thus, a feature of the invention is that the inflated balloon may be deflated through the deflation lumen when the inflation lumen is obstructed by severing the catheter shaft adjacent its proximal end and opening the deflation lumen.

Further features will become more fully apparent in the following description of the embodiments of this invention and from the appended claims.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a fragmentary elevational view of the catheter of the present invention, with a retention balloon on the catheter in a deflated condition;

FIG. 2 is a fragmentary sectional view of the catheter of FIG. 1, with the retention balloon in an inflated condition;

FIG. 3 is a sectional view taken substantially as indicated along the line 3—3 of FIG. 1;

FIG. 4 is a sectional view taken substantially as indicated along the line 4—4 of FIG. 1;

FIG. 5 is a sectional view taken substantially as indicated along the line 5—5 of FIG. 2;

FIG. 6 is a sectional view of an alternate embodiment of the present invention; and

FIG. 7 is a fragmentary perspective view, showing a catheter being severed to permit deflation of the balloon through deflation lumens of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIGS. 1–4, there is shown a catheter, generally designated **10**, including a shaft designated generally **12** having a proximal end **14**, a distal end **16**, at least one drainage eye **18** adjacent the distal end **16** of the shaft **12**, and a main lumen **12** extending from the drainage eye **18** to the proximal end **14** of the shaft **12**. The catheter **10** also has a retention balloon **22** adjacent the distal end **16** of the shaft **12**, a sidearm **24** extending outwardly from the shaft **12** adjacent its proximal end **14**, and an inflation lumen **26** extending through the sidearm **24** and the wall of the shaft **12**, such that the inflation lumen communicates between valve means **28** at the outer end of the sidearm and the inside of the balloon **22** through an opening **30** underlying the balloon.

In use, the distal end **16** of the catheter is inserted through the urethra of a patient into the bladder, and the balloon **22** is inflated in the patient's bladder by forcing fluid through the valve means **28** and inflation lumen **26** into the balloon **22** with suitable means, such as a syringe (not shown). The inflated balloon prevents the inadvertent removal of the catheter from the patient's bladder. (The balloon is shown in its inflated condition in FIG. **2**, while it is shown deflated in FIG. **1**.) While the balloon is inflated during catheterization, urine from the bladder drains through the drainage eye **18** and the main lumen **20**. The balloon is normally deflated to permit removal of the catheter from the patient by withdrawing fluid with a syringe from the balloon through the inflation lumen **26** and valve means **28**.

As previously discussed, catheters sometimes fail to properly deflate, causing a considerable amount of difficulty in removing the catheter from the patient. The catheter of the present invention has at least one, and preferably two, as shown, deflation lumens **32** extending longitudinally along the catheter shaft **12**. The deflation lumens communicate with the retention balloon and are closed adjacent the proximal end of the catheter. When the retention balloon fails to deflate, the catheter may be severed adjacent its proximal end, as shown in FIG. **7**, to open the deflation lumens **32** and permit drainage of fluid from the balloon through the deflation lumens. Thus, the balloon will deflate even if there is blockage in the inflation lumen **26** intermediate the point of severance and the balloon due to pressure exerted by the inflated balloon.

FIGS. **3** and **6** are illustrative of the cross sectional appearance of lumens **32** which may be used to deflate the retention balloon. In FIG. **6**, the lumens **32** are formed by grooves **34** in the wall of the catheter with a thin layer **35** covering the groove and defining the outer wall of the lumens **32**. This construction is preferably obtained during the manufacturing of the entire catheter, such as by a latex dipping process. Prior to the final dipping of the catheter, grooves **34** are formed in the exterior of the catheter wall, and a separating material, such as bentonite, is painted over the grooves at the same time the balloon area is coated with a separating material such that the coating is continuous between the two areas. The final dipping then produces the layer **36** and balloon **22** over the separating material, and thereafter the separating material is flushed or removed from the lumens **32** so formed.

An alternate structure for the lumens **32** is shown in FIG. **3**, in which the lumens are formed in a similar manner, except that the catheter wall has no grooves. The catheter walls are painted with a separating material, and the catheter undergoes a final dip to form the layer **36** and balloon **22** over the separating material. After the separating material is removed from under the layer **36**, the lumens **32** are defined by the layer **36** and the underlying catheter shaft.

It is possible to utilize the relatively thin layer **36** to form the outer wall of the deflation lumens **32**, since the deflation lumens **32** are not subjected to the relatively large pressure reached in the inflation lumen **26** when the retention balloon is inflated by the syringe. However, the relatively thin layer **36** bulges out slightly, as shown in FIG. **5**, when the balloon is inflated, due to back pressure into the deflation lumens **32** from the balloon. The layer **36** contracts toward the catheter shaft when the balloon is deflated, as shown in FIG. **3**. It is apparent that bulging of the deflation lumen wall **36** may serve as an indication that the balloon **22** is inflated.

Since the deflation lumens **32** and inflation lumen **26** are constructed in a different manner, the deflation lumens **32** are not subject to most of the same types of failures associated with the inflation lumen **26**, as previously described. Also, the provision of a multiplicity of lumens through which the balloon may be deflated significantly increases the probability that the balloon may be deflated at least through one of the lumens.

The foregoing detailed description is given for clearness of understanding only, and no unnecessary limitations should be understood therefrom, as modifications will be obvious to those skilled in the art.

We claim:

1. A catheter, comprising:

a shaft having a proximal end, a distal end for insertion into a body cavity, a drainage eye adjacent the distal end of the shaft, and a main lumen extending from the drainage eye to the proximal end of the shaft for draining liquid from the body cavity;

an inflatable retention balloon adjacent the distal end of the shaft for retaining the shaft in the cavity;

an inflation lumen extending between the inside of said balloon and adjacent the proximal end of the shaft;

valve means for controlling inflation and deflation of said balloon through said inflation lumen; and

at least one separate deflation lumen communicating between the balloon and adjacent the proximal end of the shaft, with the proximal end of said deflation lumen being closed and spaced from the proximal end of the catheter shaft, said deflation lumen having an outer wall defining an outer surface of the catheter shaft, and with said proximal end of the deflation lumen being separated from communication with the inflation lumen, whereby the balloon may be deflated through the deflation lumen by severing the catheter shaft and deflation lumen adjacent the proximal end of the shaft when the inflation lumen is obstructed.

2. The catheter of claim 1 wherein said shaft has a pair of deflation lumens.

3. The catheter of claim 1 wherein said deflation lumen is defined by a longitudinally extending groove in the outside of the catheter shaft and a thin layer of flexible material covering said groove.

4. The catheter of claim 1 wherein said deflation lumen is defined by a thin layer of expandable flexible material covering the catheter shaft, said layer being separated from the shaft through a longitudinally extending portion thereof.

5. The catheter of claim 1 wherein said outer wall of the deflation lumen and balloon are both a one-piece construction of flexible material covering the catheter shaft.

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,860,007 Dated January 14, 1975

Inventor(s) William J. Binard and John F. Dye

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 3, line 13, change "12" (second occurrence) to -- 20 --.

Column 3, line 61, change "35" to -- 36 -- .

Signed and sealed this 1st day of April 1975.

(SEAL)
Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents
and Trademarks

FORM PO-1050 (10-69)

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